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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

International Patent Application of

NISHIYA et al.

Atty. Ref.: 249-424

Serial No. 10/575,096

Group: 1632

Filed: April 10, 2006

Examiner: Unknown

For: PROCESS FOR PRODUCING ANTIBODY COMPOSITION BY USING RNA
INHIBITING THE FUNCTION OF (1,6-FUCOSYLTRANSFERASE

* * * * *

November 22, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1540

Sir:

SUBMISSION

Submitted herewith is a copy of the English translation of the International Preliminary Report on Patentability (Form PCT/IB/338, Form PCT/IB/373 and Form PCT/ISA/237) issued in the corresponding PCT/JP2004/015316.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

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From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

KYOWA HAKKO KOGYO CO., LTD.
6-1, Ohtemachi 1-chome
Chiyoda-ku Tokyo 1008185
JAPON

RECEIVED

AUG. 2 1. 2006

I.P. DEPT

Date of mailing (day/month/year) 03 August 2006 (03.08.2006)	
Applicant's or agent's file reference 1621	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/015316	International filing date (day/month/year) 08 October 2004 (08.10.2004)
Applicant KYOWA HAKKO KOGYO CO., LTD. et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1621	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2004/015316	International filing date (<i>day/month/year</i>) 08 October 2004 (08.10.2004)	Priority date (<i>day/month/year</i>) 09 October 2003 (09.10.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 27 July 2006 (27.07.2006)
Facsimile No. +41 22 338 82 70	Authorized officer <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div> e-mail: pt07@wipo.int

PATENT COOPERATION TREATY

TRANSLATION

PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

<div style="border: 1px solid black; width: 100%; height: 100%;"></div>		Date of mailing (day/month/year)	01.02.2005
Applicant's or agent's file reference 1621		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/JP2004/015316	International filing date (day/month/year) 08.10.2004	Priority date (day/month/year) 09.10.2003	
International Patent Classification (IPC) or both national classification and IPC C12P21/08, C12N15/10, C12N1/19, C12N5/10			
Applicant KYOWA HAKKO KOGYO CO., LTD.			

1. This opinion contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the opinion
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/015316

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____ which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/015316

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-28

YES

Claims

NO

Inventive step (IS)

Claims

YES

Claims 1-28

NO

Industrial applicability (IA)

Claims 1-28

YES

Claims

NO

2. Citations and explanations:

Document 1: WO 02/31140 A1 (Kyowa Hakko Kogyo Co., Ltd.), 18 April 2002

Document 2: WO 02/46186 A1 (Kyowa Hakko Kogyo Co., Ltd.),

Claims 1-28 do not involve an inventive step in the light of documents 1 and 2. Document 1 discloses a method for producing recombinant antibody molecules having complex N-glycoside-linked sugar chains in the Fc region in which fucose is not bound to N-acetylglucosamine in the reducing end of the sugar chain, by culturing transformants produced by introducing DNA coding an antibody molecule into cells which lack or have low activity for an enzyme which contributes to sugar chain modification whereby position 1 of fucose is α -bonded to position 6 in the N-acetylglucosamine in the reducing end of complex N-glycoside-linked sugar chains, by suppressing transcription or translation of genes for an aforementioned enzyme; it also discloses suppression by means of RNAi as a method for suppressing the translation or transcription of genes for the aforementioned enzymes. In addition, document 2 discloses a method for producing RNAi for suppressing the translation or transcription of

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/015316

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

a gene. Therefore, in order to lower or eliminate the activity of an enzyme which contributes to sugar chain modification whereby position 1 of fucose is α -bonded to position 6 in the N-acetylglucosamine in the reducing end of complex N-glycoside-linked sugar chains with reference to document 1, a person skilled in the art could easily produce RNAi which suppresses transcription or translation of an aforementioned enzyme with reference to the method for producing RNAi disclosed in document 2, and introduce DNA coding an antibody molecule into cells into which said RNAi has been introduced, to produce an antibody composition comprising recombinant antibody molecules which have complex N-glycoside-linked sugar chains in the Fc region in which fucose is not bound to N-acetylglucosamine in the reducing end of the sugar chain.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/015316

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/85118 A1 [P, X]	16.10.2003	09.04.2003	09.04.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)